

REMARKS

Claims 29, 30, and 33-40 were pending in the application. Claims 30 and 37 has been canceled, claims 29, 33, 38, 39, and 40 have been amended, and new claims 41 and 42 have been added. Accordingly, after the amendments presented herein have been entered, claims 29, 33-36, and 38-42 will be pending in the instant application. *No new matter has been added.*

Support for the amendments to the claims and for the new claims can be found throughout the specification and claims as originally filed.

Cancellation of and/or amendment to the claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The cancellation of and/or amendments to the claims are being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the instant or in another patent application.

Withdrawal of Rejections

Applicants gratefully acknowledge the Examiner's withdrawal of the rejection of claims 29 and 31-35 under 35 U.S.C. §112, second paragraph; claim 34 under 35 U.S.C. §112, second paragraph; claims 29, 31, and 35 under 35 U.S.C. 102(b); and claims 29 and 31-35 under 35 U.S.C. §103(a).

Rejection of Claims 29, 31-35, 36, and 38-40 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 29, 31-35, 36, and 38-40 under 35 U.S.C. §112, first paragraph because, according to the Examiner,

the specification while being enabling for a retroviral vector comprising a fusion nucleic acid comprising: i) an IL-4 inducible epsilon promoter with the sequence as set forth as SEQ ID NO:1; ii) a first reporter gene; iii) a nucleic acid encoding a 2a site; and iv) a second reporter gene, does not reasonably provide enablement for a retroviral vector comprising a fusion nucleic acid comprising: i) an inducible promoter or an IL-4 inducible epsilon promoter; ii) a first reporter gene; iii) a nucleic acid encoding a 2a site; and iv) a second reporter gene, for reasons of record set forth in the Office Action of 01/14/2004.

In particular, the Examiner is of the opinion that “[i]t would require undue experimentation for one of skill in the art to make and use the claimed vectors, since the skilled artisan would have to first make variants of the IL-4 inducible promoter, then test for function. Thus, since Applicant has only taught how to test for variants of IL-4 inducible promoter, and has not taught how to [*sic*] variants of IL-4 inducible promoter, it would require undue experimentation of one of skill in the art to make and use the claimed vector.”

Applicant respectfully submits that one of ordinary skill in the art would be able to make and use the claimed invention using only routine experimentation for the reasons set forth in the Amendment and Response dated April 29, 2004, and as set forth herein. In particular, contrary to the Examiner’s assertion, at the time the instant application was filed, it was conventional in the art for one of ordinary skill in the art to test IL-4 inducible promoters for function by, for example, assaying for induction of an IL-4 inducible promoter in the presence of IL-4 or IL-13. Methods for testing for IL-4 inducible promoter function are also described in Applicants’ specification. For example, as set forth in Applicants’ specification “introduction of IL-4 causes the pronounced activation of a particular DNA binding protein that then binds to the IL-4 inducible promoter segment and induces transcription” (see page 8, lines 7-9). Moreover, Applicants’ specification states that modulation of an IL-4 promoter may be measured by the

presence or quantification of transcripts or of translation products, *e.g.*, in the presence of IL-4 or IL-13 (see, for example, page 8, lines 3-18).

Therefore, it is Applicants' position that, given the guidance in Applicants' specification and the teachings in the art at the time the invention was made, one of ordinary skill in the art would be able to practice the invention as claimed using no more than routine experimentation. However, in an effort to expedite prosecution of the instant application, and in no way acquiescing to the Examiner's rejection, Applicants have amended claim 29 to refer to an IL-4 inducible promoter comprising the sequence set forth as SEQ ID NO:1. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Rejection of Claims 29, 31-35, 36, and 38-40 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 29, 31-35, 36, and 38-40 under 35 U.S.C. §112, first paragraph, as "containing subject matter which was not described in the specification in such as way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record set forth in the Office Action of 1/14/2004." In particular, the Examiner states that

[i]n the instant case there are a large number of nucleic acid sequences which are possible IL-4 inducible promoters while the specification provides the necessary guidance to make the vector with the promoter of SEQ ID NO:1, it does not provide the necessary guidance for one of ordinary skill in the art to use the vectors which do not encode function as an IL-4 inducible promoter. Further, since no functional language is associated with the vector, one of ordinary skill in the art would not know how to use these defined sequences except in further characterization of the sequences themselves."

Applicants respectfully traverse the foregoing rejection. Applicants' respectfully submit that the instant claims do not encompass all inducible promoters as stated by the Examiner at page 4 of the instant Office Action. To the contrary, the instant claims are limited to retroviral vectors comprising an ***IL-4 inducible epsilon promoter***. Furthermore, promoters which are encompassed by the claim are limited to those functional promoters which are capable of being induced by IL-4, as described in Applicants' specification, and as set forth above. Therefore, these promoters contain distinguishing functional characteristics, *e.g.*, the ability to induce transcription in the presence of IL-4. An example of the sequence of an IL-4 inducible promoter is set forth in Applicants' specification. As set forth above, the identification or production of variant nucleic acid sequences was well-known in the art at the time the application was filed. Testing the variant promoters for the ability to be induced by IL-4 was also known to those of skill in the art and is described in Applicants' specification. Thus, based on the teachings in Applicant's specification, one of skill in the art would conclude that Applicants were in possession of the claimed invention at the time of filing.

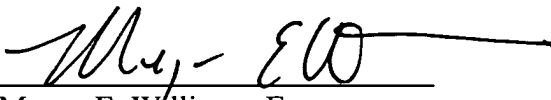
However, in an effort to expedite prosecution of the instant Application, and in no way acquiescing to the Examiner's rejection, Applicants have amended claim 29 to refer to an IL-4 inducible promoter comprising the sequence set forth as SEQ ID NO:1. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

CONCLUSION

If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

By: 
Megan E. Williams, Esq.
Registration No. 43,270
Attorney for Applicants

28 State Street
Boston, MA 02109
(617) 227-7400
(617) 742-4214

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